K 131014

NSK America Corporation

5. 510(k) SUMMARY

Submitter:	NSK America 1800 Global Parkway Hoffman Estates, IL 60192
510(k) Owner / Contact Person:	Hirohiko Murase Executive Vice President and General Manager TEL: 847-843-7664 FAX: 847-843-7622 murase@nskamericacorp.com
Date Prepared:	April 5, 2013
Trade Name:	PANA SPRAY Plus
Common Name:	Handpiece Lubricant
Classification Name:	Handpiece, Air-Powered, Dental (21 CFR 872.4200, Product Code FMC)
Classification:	Class 1
Predicate Device:	K052700 NSK America Pana-Spray
Device Description:	*PANA SPRAY Plus* is an alcohol-based general handpiece and air-motor lubricant. The lubricant is introduced into the handpiece through the air-drive pipe or the back end. *PANA SPRAY Plus* can be used for the maintenance of high speed handpieces, low speed handpieces, and air motors and should be used after each patient and prior to sterilization of handpiece and air motors.
Statement of Intended Use:	*PANA SPRAY Plus* is a lubricant intended to be used during routine maintenance of dental and surgical handpieces after each patient use and prior to sterilization.
Summary of Technological Characteristics:	Both the proposed PANA SPRAY Plus and the predicate Pana Spray are lubricants provided in aerosol cans for the maintenance of dental handpieces and air motors. The method of delivery, function, and performance of the proposed and predicate devices are the same.
Summary of Non-Clinical Data: Test Data:	PANA SPRAY Plus was evaluated to confirm that the device met NSK America internal requirements for reliability (package vibration, unit drop, and temperature testing) and durability (repeated usage, actual usage, and contra/turbine testing). The test results indicate that PANA SPRAY Plus met all NSK America internal requirements and is therefore substantially equivalent to the predicate device.
Conclusion:	*NSK America* considers *PANA SPRAY Plus* to be substantially equivalent to the predicate device(s) listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

AUG 12 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 12, 2013

NSK America Corporation
C/O Ms. Diane Rutherford
Ken Block Consulting
1201 Richardson Drive, Suite 280
Richardson, Texas 75080

Re: K131014
Trade/Device Name: PANA SPRAY Plus
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: July 17, 2013
Received: July 18, 2013

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K131014

Device Name: *PANA SPRAY Plus*

Indications for Use:

PANA SPRAY Plus is a lubricant intended to be used during routine maintenance of dental and medical surgical handpieces after each patient use and prior to sterilization.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.08.07 15:52:49 -04'00'

for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K131014